FEB 2 7 2002

K013941

SECTION 11

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Submitter's name, address, telephone number, contact person, and date summary prepared;**

   a. Applicant: IntraLase Corp.
   3 Morgan
   Irvine, CA 92618

   b. Contact Person: J. Randy Alexander
   President and CEO

   c. Date Summary Prepared: November 26, 2001

2. **Name of device, including trade name and classification name:**

   a. Trade/Proprietary Name: Pulsion FS Laser

   b. Classification Name: Laser Keratome

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Company:	IntraLase Corp.
Device:	Pulsion FS Laser
510(k):	K993153
Date Cleared:	December 17, 1999

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The Pulsion FS Laser is a precision ophthalmic surgical laser designed for use in performing lamellar corneal resections. The cutting action of the *PULSION FS* Laser is achieved through precise individual micro-photodisruptions of tissue, created by tightly focused ultrashort pulses which are delivered through a disposable applanation lens while fixating the eye under very low vacuum.

5. Statement of intended use:

The Pulsion™ FS is an ophthalmic surgical laser indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The technological characteristics of the Pulsion FS Laser have already been cleared under K993153 for lamellar corneal resections. The design, materials, and characteristics of the laser keratome are the same irrespective of the indication for use.

7. Brief summary of nonclinical tests and results:

The Pulsion FS Laser has undergone testing and is in compliance with applicable safety standards. In addition, the Pulsion FS was found to perform equivalently to the predicate laser keratome, with respect to the creation of corneal resections in extensive *ex vivo* and *in vivo* studies. Thus, the Pulsion FS Laser and the predicate device have similar safety, effectiveness or performance profiles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2002

IntraLase Corporation
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
2 Delphinus
Irvine, California 92612

Re: K013941
Trade/Device Name: Pulsion FS Laser Keratome
Regulation Number: 878.4810, 886.4370
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Keratome
Regulatory Class: II
Product Code: GEX, HNO
Dated: November 26, 2001
Received: November 29, 2001

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

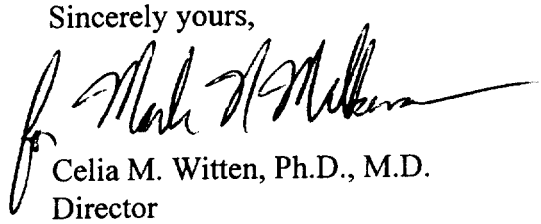
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013941

Device Name: Pulsion FS Laser

Indications for Use:

The Pulsion™ FS is an ophthalmic surgical laser indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use X OR Over-The-Counter Use ____
(Optional Format 1-2-96)

for Mark A. Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013941

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